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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/800,984 | 03/15/2004 | Nirmal Mulye | 14276 | 2376 |

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| EXAMINER | |
|---|---|
| WESTERBERG, NISSA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
|---|---|---|
| | *10/800,984* | MULYE, NIRMAL |
| | **Examiner** | **Art Unit** |
| | NISSA WESTERBERG | 1618 |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 20 September 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *20 September 2011*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *38,40-48,54-56,59,60 and 63-73*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Nissa M Westerberg/
Primary Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 38, 40 - 47, 54 - 56, 59, 63 - 66 and 71 - 73 were rejected under 35 USC 103(a) as being unpatentable over Shell et al. (US 6,340,475) in view of Seroff et al. (US 6,387,403). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 20, 2011 and those set forth below.

Applicants traverse this rejection on the grounds that four components (drug, sustained release carrier, water insoluble or partially water insoluble cellulose and maltodextrin) must be present in the core and could not form a homogenous mixture unless the maltodextrin is present. Shell and Seroff each to do not teach all of the elements of the instant clams. The Office has engaged in hind sight analysis and ignored the teachings of Seroff that the maltodextrin and swellable polymers are present in different layers and thus the ingredients will not interact. The combination requires reconstruction and redesign of the elements of Seroff and a change in the basic principles of operation. Maltodextrin is stated to be a chemical stabilizer of reboxetine, the drug in Seroff, and Shell relates to drugs in general.

1. These arguments are unpersuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As explained in greater detail in the previous office Action, both the drug delivery dosages forms of Shell and Seroff operate on the principle of water imbibition by the device leading to drug release. Shell does not use the bilayer structure and thus has the water swellable polymer in the same layer as the drug. While maltodextrin is stated to produce a more stable formulation with reboxetine than other excipients, this does not negate the teaching of maltodextrin as an osmagent but rather suggests that for reboxetine, maltodextrin would be the osmagent of choice. It is the function of maltodextrin as an osmagent that motivates the inclusion of this ingredient into the core of the dosage form of Shell. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). No reconstruction or redesign of the dosage form of Seroff is required beyond that which is taught by the primary reference of Shell and both operate on the same principle mentioned above - the imbibition of water into the dosage form in the use environment that brings about drug release. Applicant's allegation that a homogenous core cannot be produced unless maltodextrin is present is not persuasive because no evidence has been provided to support this allegation and the core taught by the combined prior art can for a homogenous mixture as it contains maltodextrin.

Applicant also argue that there is no teaching or suggestion in either reference that maltodextrin and water insoluble or partially water insoluble cellulose will affect the rate of release of the drug.

This argument is unpersuasive. The release rate will be determined the structure and ingredients present in that structure. The same structure and ingredients as required by the instant claims are taught by the applied prior art. A limitation stating the mechanism by which the product operates, that may not have been appreciated by the prior art, does not render the composition patentable (see MPEP 2112).

Claims 48 and 67 - 70 were rejected under 35 USC 103(a) as being unpatentable over Shell and Seroff further in view of Tobyn (Intl J Pharm, 1998). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed May 20, 2011 and those set forth below.

Applicant traverses this rejection on the grounds that in addition to Tobyn not curing the deficiencies of Shell and Seroff discussed above, there is no reason to combine the cited references. None of the cited art recognizes that maltodextrin or silicified maltodextrin [The Examiner has assumed that Applicant meant silicified microcrystalline cellulose] prolongs the release of drug from the formulation and thus are not linked to the advantages described in the instant specification regarding the rate of release of the drug or interacting with maltodextrin, fine tuning the release of the drug. It is impermissible hindsight to use the known excipient silicified MCC.

These arguments are unpersuasive. Shell and Seroff were addressed above and not found to be deficient as alleged by the Examiner. The reasoning cited by the Examiner need not be the same reason that Applicants had for adding a particular element to a composition. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). While the applied prior art does not appreciate the change in release properties that accompanies the addition of maltodextrin and/or silicified MCC, such properties necessarily flow from their addition to the composition as set forth previous and appreciation of those effects does not render the composition patentable.